United Fresh Fruit and Vegetable Association
Comments Regarding
the
United States Department of Agriculture Agricultural Marketing Service Microbiological Data Program

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In November 2000, the Agricultural Marketing Service (AMS) notified the produce industry of its intent to implement a Microbiological Data Program (MDP). The purpose of the program is to provide baseline information about pathogens and indicator organisms on fresh fruits and vegetables in the United States through the collection and testing of produce commodities at the retail level. To assist with the implementation of this, Congress provided $6.235 million to establish the MDP. Additionally, P. L. 107-76, the FY 2002 Agriculture spending measure contains an additional $6 million to continue implementation of the program.

The produce industry is proud of the contribution it makes to the health of Americans by providing foods that are wholesome and essential for good health. It is important to consider that increasing the consumption of fresh fruits and vegetables is a critical component of a healthy lifestyle. While the risk of foodborne illness associated with produce is small, and in fact a vast majority of produce commodities have never been linked to outbreaks of illness, the produce industry is keenly interested in limiting this risk. The produce industry wholeheartedly supports any information or guidance based on sound scientific results that can help the industry enhance the safety of produce, enhance consumer confidence, and increase the consumption of fresh fruits and vegetables which has documented health benefits.

The U.S. Department of Agriculture (USDA) has a long history of providing valuable support and assistance to the fresh fruit and vegetable industry. Within the USDA, the fruit and vegetable industry also has a long-standing appreciation for the valuable services provided by the AMS. Over the last several years, the produce industry has developed several programs to enhance the safety of fresh fruits and vegetables. The regulatory attention to potential concerns regarding microbiological safety of fresh fruits and vegetables has increased substantially in the recent years. The produce industry continues to work with all sectors of the federal government to address these concerns.

However, as the produce and retail industries have become more educated and informed about the MDP, several concerns have been identified including implementation issues and clearly defined and measurable goals and objectives of the program. Most notably, there is still no clear indication of how the information collected by the AMS will be used by state and federal agencies. Further disconcerting is the fact that AMS has not sought any substantial, non-governmental, objective review of the program, sampling methods, or ultimate, specified use of the data.

Additionally, there are serious questions regarding the sampling methods that will be used and validity of the data obtained from the MDP for risk assessment purposes. There still continues to be the uncertainty of what question or problem this survey will solve. Is the intent, to receive federal funds, develop a program, and then ask what problem exists and who can use the information that results? Furthermore, any microbiological sampling program should be designed in a manner to ultimately achieve a reduction in foodborne illnesses. The MDP should be more than data collection. A well thought-out plan of how the data will be used should be developed. No one wants to waste tax dollars on a program that collects data just to have a set of numbers. Therefore, the $6.235 million currently obligated for the MDP should be allocated so that the resulting data can be used by the Food and Drug Administration (FDA), the Agricultural Research Service (ARS), and more importantly the produce industry to advance our collective understanding of produce safety and to identify research needs for the future.

Another issue of concern regarding the MDP is that it would seem to set AMS on a new and unprecedented course in the area of microbiological sampling. The authority to inspect fruit and vegetable products for adulteration, which would include microbial profiles, is appropriately granted to the FDA. The produce industry believes that it is a significant legal stretch to interpret the language of the Agriculture Marketing Act as giving AMS additional authority in the area of microbiological data collection without any of the careful balances contained in the inspection authority granted under the Food, Drug, and Cosmetic Act (FFDCA). Consequently, the produce industry supports the FFDCA, which provides ample authority to the FDA to assure the safety of fresh fruit and vegetables.

The produce industry supports programs that will accurately identify and put into context the risks of illnesses associated with specific foods and handling practices. The focus and discussion of foodborne illnesses seem to shift and intensify according to prevailing fads. One day seafood is the prevailing concern; the next, eggs; and then fresh fruits and vegetables. Similarly, during the course of public discussion regarding specific foods, there is a lack of proper context regarding the practices that cause the majority of illnesses. Too often the most enthusiastic public discussions among health officials and researchers focus on the unique and least common foodborne illness events. Therefore, data should be generated to perform a risk assessment that would provide tools to manage the risk. The sample collection, analytical methods and procedures used should be well thought out and discussed with experts in risk assessment and risk management so that the data generated will ultimately be used to develop new strategies to further reduce the incidence of food borne illnesses. AMS should review the attempts made by other federal

agencies to perform risk assessment and adopt models that will be beneficial to the consumers.

While the risks of foodborne illness associated with produce is small in comparison to other food items, the produce industry is very interested in cooperating with researchers to devise effective, economical ways to further limit those risks.

For the produce industry, there are many important questions regarding when and at what point in the distribution chain should sampling be performed. Ultimately, the answer must be that sampling should be performed in a manner that will produce the most scientifically reliable results for the purpose of minimizing the risk of foodborne illness.

Based on the guidance document, FDA¡¦s Center for Food Safety and Applied Nutrition (CFSAN) determined they needed more data on the incidence and extent of pathogen contamination for selected fresh domestic and imported produce to assist in the development of additional policy for the Produce Safety Initiative. FDA¡¦s purpose is not to attempt to detect every incidence of low, level sporadic contamination. Their purpose, rather, is to detect those levels of contamination that might result from a failure to follow adequate GAPs and GMPs. The objectives of the FDA project were well defined and straightforward. The FDA will collect and analyze samples of domestic and imported fresh produce and determine the incidence of microbial contamination on those commodities previously linked to foodborne illness outbreaks.

Finally, since 1997, FDA has done similar surveys and sampling of domestically grown fresh fruits and vegetables including:

- Assignment to Inspect Sprout Growers and Collect Samples of Alfalfa, Radish, Broccoli and Mung Beans
- Assignment to Inspect Manufacturers of Fresh, Unpasteurized Apple Juice/Cider
- Assignment to Assure Unpasteurized Juice Manufacturers and Imported Juice Products Provide Required Label Warnings, Placards, and/or Meet the 5-Log Pathogen Reduction Requirement; and,
- Prepared Cut Vegetable Salad Manufacturers Survey

In summary, over the last four years, the produce industry has participated extensively in sampling and survey programs with the federal government and continues to do so. The question remains as to whether another sampling program by yet a different federal agency will serve the need to increase understanding and analysis of food safety concerns? How will the MDP program compliment or compete with the FDA domestic and import sampling requirements. Are the sampling protocols consistent in order to compare data from both agency's sampling programs? It is our present belief that these AMS efforts are duplicative of the actions of the FDA CFSAN's produce microbiological sampling programs currently underway. If additional information or samples are needed

to enhance the current FDA produce sampling programs, then FDA should have been given the necessary funds to further expand them instead of reinventing a sampling program in yet another federal agency.

Despite these differences, past experiences have taught us that effective public-private partnerships are the most effective way of developing sound public policy and priorities to address tough policy issues. In addition, the produce industry continues to support the federal government's interest in collecting research data than can be offered to the scientific community, industry and non-regulatory bodies to evaluate the scope of the problem and offer additional research vital to mitigation strategies. Produce industry members are eager to resolve issues associated with food safety where evidence indicates that problems exist and propose appropriate solutions.

Unfortunately, the MDP has given the industry little reason to believe that it will provide new or current information toward the goal of safer fresh produce. However, the industry is interested in working with the USDA and Congress to tailor programs to enhance and augment current efforts underway by the federal government.